REMARKS

Claims 81-83, 89 and 90 have been canceled. Claim 84 was previously cancelled. Thus, claims 85-88 are now pending in the application. Reconsideration and withdrawal of the present rejections in view of the amendments and comments presented herein are respectfully requested.

Rejection under 35 U.S.C. § 112, 1st paragraph

The Examiner rejected Claim 82 under 35 U.S.C. § 112, first paragraph, as lacking enablement. Claim 82 has been canceled herein, thus rendering the rejection moot.

Discussion of Rejection under 35 U.S.C. § 103 – Obviousness

The Examiner rejected Claims 81-83 and 85-90 under 35 U.S.C. § 103(a) as being unpatentable over Lidsky (US Patent No. 5,602,150) in view of Vetulani (Review Drug Addiction. Part III. Pharmacotherapy of Addiction, *Polish Journal of Pharmacology*, 2001, Vol. 53, pp. 415-434), in view of Bormann et al. (US Patent No. 5,061,703) and further in view of Decollogne et al. (NMDA Receptor Complex Blockade by Oral Administration of Magnesium: Comparison with MK-801, 1997, *Pharmacology Biochemistry and Behavior*, Vol. 58, No. 1, pp. 261-268). Claims 81-83, 89 and 90 have been canceled herein, thus rendering the rejection moot as it applies to these claims. The rejection will be addressed as it applies to claims 85-88.

The Examiner argues that it is *prima facie* obvious to combine two compositions (i.e., acamprosate and magnesium), each of which is taught to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. A *prima facie* case of obviousness cannot be maintained, however, if the combination has unexpected results such as a synergistic effect.

It has long been established that secondary considerations such as unexpected results are relevant to the determination of non-obviousness. *See, for example, Graham v. John Deere, Co.*, 383 U.S. 1, 17 (1966). "Evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." *See Stratoflex Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). Here, secondary considerations, specifically unexpected results, are provided in the application combined with the enclosed Rule 132 Declaration of Barry S. Fogel, M.D. This objective evidence of unexpected results demonstrates that the instant claims are not obvious.

As demonstrated by Case Reports 2-5 in the present specification at pages 26-45, and echoed in the Declaration of Barry S. Fogel, M.D., the combination of acamprosate and magnesium was significantly better at alleviating TD symptoms than was acamprosate alone. Importantly, the administration of magnesium alone had no effect in alleviating such symptoms (Declaration at paragraphs 4 and 5). In particular, when the patient described in Case Report 5 was administered magnesium alone, no improvement in symptoms was observed (Declaration at paragraph 5). Since magnesium alone had no beneficial therapeutic effect, it would be expected that the combination of magnesium and acamprosate would result in no additional therapeutic efficacy compared to acamprosate alone. However, when the patient described in Case Report 5 was administered magnesium and acamprosate, the combination resulted in a greater than additive (i.e., synergistic) effect since significant improvements in symptoms were observed compared to acamprosate alone. This would not have been expected based on the lack of therapeutic efficacy of magnesium. The combination of acamprosate and magnesium also resulted in significant improvements compared to acamprosate alone in Case Reports 2-4. In view of the lack of therapeutic efficacy of magnesium alone, these results also demonstrate the synergistic effect of acamprosate and magnesium.

Thus, the case studies and Declaration provide objective evidence of non-obviousness because they demonstrate unexpected results from the combination of acamprosate with magnesium, specifically synergy in improvement of symptoms associated with movement disorders such as TD.

For the above reasons, Applicant submits that Claims 85-88 are not obvious over the cited references. Thus, Reconsideration and withdrawal of the rejection under 35 U.S.C. § 103 are respectfully requested.

Conclusion

Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. In view of the above amendments and remarks, the present application is believed to be in condition for allowance, and action to that effect is respectfully solicited. Applicant invites the Examiner to call the undersigned if any issues may be resolved by telephone.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: October 27, 2006

By: _____

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